

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

IN RE SUBOXONE (BUPRENORPHINE HYDROCHLORIDE AND NALOXONE) ANTITRUST LITIGATION

MDL NO. 2445
13-MD-2445

THIS DOCUMENT RELATES TO:

Wisconsin, et al. v. Indivior Inc. et al.
Case No. 16-cv-5073

STATE OF WISCONSIN

By Attorney General Brad D. Schimel, *et al.*

CIV. A. NO. 16-5073

Plaintiffs,

V.

**INDIVIOR INC. f/k/a RECKITT BENCKISER
PHARMACEUTICALS, INC., et al.**

Defendants.

MEMORANDUM

Goldberg, J.

December 3, 2021

Currently before me in this multi-district antitrust case is the End-Payor Plaintiffs’ (“EPPs”) second request for approval of the form and manner of their proposed notice to prospective class members. I denied the EPPs’ original Notice Plan. Having now amended their Notice Plan, the EPPs file this Renewed Motion for Approval of Notice. Defendant Indivior, Inc. again opposes this Motion, identifying numerous alleged deficiencies. For the following reasons, I will grant the EPPs’ Motion and approve their Amended Notice Plan.

I. RELEVANT FACTUAL BACKGROUND¹

Defendant Indivior, Inc. (“Defendant”) manufactures Suboxone, a drug commonly used to combat opioid addiction. Suboxone previously came in tablet form, but in 2010, citing safety concerns, Defendant effectuated a change in the administration of this drug, switching from tablet to sublingual film. Various purchasers/consumers of Suboxone claimed that this switch was anticompetitive and solely designed to maintain Defendant’s market exclusivity—a scheme known as a “product hop.” These claims have resulted in multi-district, antitrust litigation before this Court.

On September 27, 2019, I certified a class of End Payor Plaintiffs pursuant to Federal Rule of Civil Procedure 23(c)(4) on six distinct issues:

1. Whether Defendant engaged in anticompetitive and deceptive conduct;
2. Whether Defendant willfully maintained monopoly power through such conduct;
3. Whether Defendant had a specific intent to monopolize;
4. Whether Defendant had a dangerous probability of achieving monopoly power;
5. Whether Defendant has offered a non-pretextual pro-competitive justification that could not have been obtained through less restrictive means, and if so;
6. Whether the anticompetitive effects of Defendant’s conduct outweigh their proffered procompetitive benefits, if any.

In re Suboxone Antitrust Litig., No. 13-md-2445, 2019 WL 4735520 (E.D. Pa. Sept. 27, 2019). The United States Court of Appeals for the Third Circuit affirmed this certification on July 28, 2020. In re Suboxone Antitrust Litig., 967 F.3d 264 (3d Cir. 2020).

On September 2, 2021, I denied the EPPs’ original motion seeking approval of their Notice Plan due to the Plan’s failure to provide for individualized notice to the consumer portion of the End-

¹ I incorporate by reference the factual history and regulatory background set forth in my prior decision certifying a class for both the DPPs and EPPs. In re Suboxone Antitrust Litig., 421 F. Supp. 3d 12 (E.D. Pa. 2019), aff’d, 967 F.3d 264 (3d Cir. 2020).

Payor Class. Accordingly, on October 4, 2021, the EPPs filed the current Second Motion to Approve the Form and Manner of Notice to the End Payor Class.

II. DISCUSSION

The EPP class is comprised of two types of class members: (a) third-party payors, who are health and welfare plans or insurance companies that pay and/or reimburse for prescription drug purchases of their members, and (b) consumers, who are individuals that purchase prescription drugs.

As to the third-party payors, the Amended Notice Plan continues to propose sending direct notice via U.S. First Class mail to reasonably identifiable third-party payors (“TPPs”), including entities such as insurance companies, health maintenance organizations, and self-insured entities. That direct notice will be supplemented with a digital ad program on ThinkAdvisor.com/life-health, as well as using Google Display Networks, Google AdWords, Facebook, and Instagram, which will be designed to reach unidentified third-party payors.

As to the consumers, the EPPs propose to utilize two forms of notice. First, the EPPs will provide direct notice by email or First Class U.S. mail to Class Members identified by Pharmacy Benefit Managers (“PBM”s) and other entities through subpoenas issued by Class Counsel. Notice Administrator A.B. Data, Ltd. (“A.B. Data”) will utilize the names and addresses of consumer class members produced in response to subpoenas that Class Counsel will serve on the top six PBMs, the ten largest TPPs, the top ten chain store pharmacies, and the top five mail order pharmacies in the United States.

Second, the EPPs will use a targeted publication campaign comprised of digital media and earned media. The EPPs plan to place digital banner, text and/or newsfeed ads through Google Display Networks and Google AdWords, social media platforms Facebook and Instagram, and specifically targeted medical networks including websites like WebMD.com. Spanish language banner ads will run on appropriate Hispanic websites. This digital network and social media

campaign will run for thirty days and will be monitored to ensure success and optimize the number of impressions delivered across each platform to achieve maximum engagement and efficiency. The EPPs also propose to issue a news release via PR Newswire's US1 and Multi-cultural Newswire distribution lists, which will be distributed to the news desks of approximately 10,000 newsrooms. The EPPs have designated A.B. Data as the notice administrator tasked with effectuating notice of this class action lawsuit to both the third-party payors and the consumer class members.

Defendant again opposes the EPPs' Motion, noting four alleged defects: (1) the EPPs' proposed order is silent regarding any schedule for providing individualized notice to consumers; (2) the Amended Notice Plan is "vague or contradictory" as to how direct notice to consumers will be accomplished; (3) the End Payors should be required to report successful completion of their proposed plan and maintain records of who has been notice; and (4) the Notice does not protect patient privacy.

A. Schedule for Individualized Notice

Defendant first argues that the Amended Notice Plan proposed by the EPPs fails to include a schedule for providing individualized notice to the consumers. Defendant notes that the only scheduling provisions relate to publication notice and to notification of TPP class members and that, in order to ensure that this case is not unduly delayed, a proposed schedule should be included.

The EPPs address this concern and provide several proposed dates to include in their Amended Notice Plan:

1. Subpoenas requesting the names, mailing addresses, and email addresses of potential consumer class members will be served on the top six PBMs, the ten largest TPPs, the top ten chain store pharmacies, and the top five mail order pharmacies within twenty-one (21) days of the Order approving the Motion.
2. A period of ninety (90) days will be permitted to allow for subpoena responses and for A.B. Data to disseminate class notice to consumers via email and/or mail.

3. Consumer class members will have a forty-five (45) day period in which to opt out of the class.

I find that these proposed timelines adequately address Defendant's concerns regarding a schedule. Accordingly, I will include them in the Order approving the Amended Notice Plan.

B. Details Concerning Subpoena and Direct Notice Procedure

Defendant next argues that the "Direct Notice" section of the Notice Plan for the consumer class members fails to describe the steps needed to identify the class members through subpoenas. Defendant identifies six purported deficiencies/inconsistencies.

First, Defendant argues that the Notice Plan fails to identify the top PBMs, TPPs, chain pharmacies, or mail order pharmacies that will receive the subpoenas. Moreover, Defendant posits that the EPPs have failed to provide copies of the subpoenas they intend to serve.

Defendant has identified no legal authority that imposes such requirements. Nonetheless, the EPPs, in an effort to "avoid further meritless protest" from Defendant, identify the proposed subpoena recipients as follows: the top six PBMs by market share (CVS Caremark; Express Scripts, Inc; OptumRx, Inc; Humana Pharmacy Solutions; MedImpact Healthcare Solutions, Inc.; and Prime Therapeutics, LLC), the ten largest TPPs by direct written premiums (UnitedHealth Group; Kaiser Foundation; Anthem, Inc; Centene Corp; Humana; CVS Health; Health Care Service Corporation; Cigna Health; Molina Healthcare, Inc; and Independence Health Group), the top ten chain store pharmacies by total prescription revenue in 2017 (CFS Health; Walgreens/Boots; Walmart; Rite Aid; Kroger; Albertsons Companies; Costco; Ahold Delhaize; Publix; and H-E-B), and the top five mail order pharmacies by total prescription revenue in 2017 (CVS Health; Express Scripts; OptumRx/UnitedHealth Group; Humana Pharmacy Solutions; and Diplomat Pharmacy). I find this disclosure sufficient to allay Defendant's concerns.

Second, Defendant presses that because the data sought is protected by the privacy laws in the Health Insurance Portability and Accountability Act (“HIPAA”), the Court would need to issue subpoenas pursuant to 45 C.F.R § 164.512(1)(1). Defendant claims, however, that the EPPs have not yet moved the Court for a HIPAA-compliant subpoena or protective order.

Again, there is no legal authority for Defendant’s proposition that such a motion for a HIPAA-compliant subpoena is a prerequisite to court approval of the form and manner of notice to the class. Indeed, a HIPAA-compliant protective order already exists in this case (ECF No. 86), and I have authority, under 45 C.F.R. 164.512(e)(1) to issue a subpoena, upon appropriate motion, compelling disclosure of HIPAA-protected information.

Third, Defendant argues that when responses to the thirty-one subpoenas are received, someone will need to sort through the data in order to determine which individuals are class members and to compile a mailing list. According to Defendant, such a task requires outside experts and, although the EPPs have proposed hiring OnPoint Analytics, they have not yet retained them or any other consultant.

This argument has no bearing on whether the Amended Notice Plan should be approved. As noted by the EPPs, Defendant conflates notice with ascertainability. The EPPs burden at this stage is to ensure notice to as many potential class members as possible. See Nichols v. SmithKline Beecham Corp., No. 00-cv-6222, 2005 WL 950616, at *9 (E.D. Pa. Apr. 22, 2005) (holding that, under Federal Rule of Civil Procedure 23, notice to class members must be “reasonably calculated under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections”). “The Notice proposed by [the EPPs] is merely a notice of the *pendency* of the class action and does not guarantee that an individual receiving a mailed-Notice is entitled to participate. Alberton v. Commonwealth Land Title Ins. Co., No. 06-cv-3755, 2010 WL 1049581, at *4 (E.D. Pa. Mar. 17, 2010). Defendant’s contention that the EPPs must engage in further

action to limit the proposed mailing list goes to the “manageability” of the potential class, which is an issue I already addressed during class certification proceedings. The potential over-inclusiveness of the intended notices does not bear on the propriety of the Amended Notice Plan.

Fourth, Defendant notes that the Amended Notice Plan calls for notice “by email or First-Class U.S. Mail,” while the accompanying declaration from A.B. Data’s representative makes no mention of notice by email.

This minor inconsistency is of no moment. The Amended Notice Plan—which is the operative document—clearly provides that notice is to be provided by email for potential consumer class members with a valid, deliverable email address, and by postal mail for potential consumer class members without such an email address. (ECF 775-2, at 20.) As I recognized in my prior Memorandum Opinion, individualized notice may properly be provided by first-class mail or email, so long as it is, in fact, individualized notice. In re Suboxone Antitrust Litig., No. 13-md-2445, 2021 WL 3929698, at *7 (E.D. Pa. Sept. 2, 2021).

Fifth, Defendant observes that the Amended Notice Plan states that “[i]f Class Members are reached through direct notice, the number of digital impressions needed can be adjusted” in the notice-by-publication part of the plan. (ECF No. 775-2 at 25.) Defendant contends that if the publication plan is to be adjusted, the Amended Notice Plan needs to specify when the adjustments will be determined, how they will be determined, and why the specific adjustments to be made are appropriate.

I need not address this speculative issue now. Should the EPPs seek, in the future, to alter the notice-by-publication part of the plan, they will need to seek Court approval and Defendant will have an opportunity to object.

Finally, Defendant asserts that the Amended Notice Plan contains no discussion of any follow-up for notices that are returned as undeliverable. According to Defendant, courts typically require additional steps to notify those class members.

I find no such deficiency in the Amended Notice Plan. “Courts have consistently recognized that due process does not require that every class member receive actual notice so long as the court reasonably selected a means likely to apprise interested parties.” In re Prudential Ins. Co. of Am. Sales Pracs. Litig., 177 F.R.D. 216, 231–32 (D.N.J. 1997) (collecting cases). “For those whose names and addresses cannot be determined by reasonable efforts, notice by publication will suffice under Rule 23(c)(2) and under the due process clause.” Id. at 232 (citing Mullane v. Central Hanover Bank Trust Co., 339 U.S. 306, 317–318 (1950)). “Rule 23 does not require the parties to exhaust every conceivable method of identifying the individual class members.” Id.

The Amended Notice Plan provides for individual notice by email and direct mail. If a potential class member does not have an identifiable, valid email address or if email notice is returned as undeliverable, notice will be sent by regular mail. For potential consumer class members whose notices are returned as undeliverable via mail, A.B. Data will employ its standard procedure of address tracing and re-mailing the notice. (ECF No. 777-2, Decl. of Eric Schlacter, ¶ 9.) Finally, the Amended Notice Plan contains an extensive notice by publication plan. Such efforts are consistent with the requirements of due process.

Accordingly, I find that the EPPs have adequately addressed all of Defendant’s concerns and I will not withhold approval of the Amended Notice Plan on any of these grounds.

C. Whether the EPPs Should be Required to Report Successful Completion of their Proposed Plan and Maintain Records of Who Has Been Noticed

In their next challenge to the Amended Notice Plan, Defendant contends that the EPPs should be required to file a declaration or “close-out report” confirming that notice has been provided to all end payor class members and identifying to whom it was sent. Defendant identifies several reasons

for the importance of this report: (a) a report of completion of notice activities and the opt-out period will allow the Court to know when to issue summary judgment rulings; (b) a close-out report will provide assurances that the class members' due process rights have been upheld; (c) the eventual judgment in this case must "include and specify or describe those to whom the Rule 23(c)(2) notice was directed" Fed. R. Civ. P. 23(c)(3)(B); and (d) the report will be useful to show the binding effect of this class action should class members seek to file additional lawsuits.

The EPPs have affirmatively represented that EPP Counsel and A.B. Data will submit copies of all Requests for Exclusion from the Class to the Court and to Defendant's Counsel, and EPP Counsel will include a Declaration verifying that the Notice Plan has been successfully implemented. Such a representation is sufficient to address Defendant's concerns.

D. Whether the Notice Plan Fails to Protect Patient Privacy

Defendant's final objection to the Amended Notice Plan contends that it fails to articulate how EPP counsel will protect the medical records of its class members, who are patients suffering from addiction. Defendant engages in a lengthy argument regarding how addiction patients suffer from serious stigma that often threatens their willingness to seek to treatment and causes other psychological problems. It notes that Congress, recognizing these concerns, has enacted a law to protect certain "[r]ecords of the identity . . . or treatment of any patient which are maintained in connection with the performance of any . . . activity relating to substance use disorder . . . treatment" 42 U.S.C. § 290dd-2(a). Defendant then posits that, to adhere to the policy underlying the confidentiality statute, the EPPs, prior to serving their subpoenas, must make an "application showing good cause therefore," 42 U.S.C. § 290dd-2(b)(2)(C), which must permit a judicial finding that "the public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services." 42 C.F.R. § 2.64(d)(2).

According to Defendant, nothing in the EPPs’ Motion or submissions addresses these issues and describes how the needed disclosures will be limited to only the necessary information. Ultimately, Defendant concludes that “[b]ecause any Notice Plan will put patients’ prescription histories into the hands of strangers, EPP counsel must take great care to ensure that their Notice Plan minimizes this violation of their clients’ privacy. Having failed to do so, they have once again submitted a deficient Notice Plan.” (Def.’s Opp’n 11.)

While Defendant’s concern for class members’ privacy is not unfounded, these privacy issues appear to have been considered and provided for by the Amended Notice Plan. A.B. Data has experience in over thirty pharmaceutical end-payor class action administrations—all of which involved sensitive health information—and has been able to secure the necessary data security clearances and nondisclosure agreements. (Schlacter Decl. ¶¶ 3–4.) The subpoenas issued to the PBMs, TPPs, and pharmacies will request names, mailing addresses, and email addresses of potential consumer class members but will not seek information about any specific purchases or transactions. (Id. ¶ 6.) Direct mailing notices will be formatted as a double-postcard that will prevent the contents from being visible, which is fully compliant with HIPAA. (Id. ¶ 8.) Moreover, A.B. Data has represented that it has “extensive security safeguards in place to ensure the privacy of consumers’ data,” including entering into non-disclosure agreements with subpoenaed parties to protect data collected and undergoing physical, logistical, data, and information systems security reviews and audits to ensure that it is HIPAA-compliant. (Id. ¶ 10.) A.B. Data acknowledges that “it will receive personal health information protected by HIPAA, and it will take all steps necessary to comply with its obligations under HIPAA and other relevant guidelines.” (Id.)

Given these representations, Defendant’s concerns that EPP counsel will violate confidentiality protections is speculative. EPP Class Counsel and A.B. Data have provided sufficient assurances for purposes of approval of the Amended Notice Plan. Before obtaining subpoenas, the

EPPs may need to more conclusively establish that other ways of obtaining the information are unavailable or ineffective and that the public interest and need for disclosure outweigh the potential injury to the patient and treatment services. See 42 U.S.C. § 290dd-2(b)(2)(C); 42 C.F.R. § 2.64(e). At this juncture however, and for purposes of approving the form and manner of notice to potential class members, I am satisfied that the EPPs have met these standards.

III. CONCLUSION

In light of the foregoing, I find that the EPPs' Amended Notice Plan sufficiently establishes that the EPPs will be issuing "the best notice that is practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort." Fed. R. Civ. P. 23(c)(2)(B). Defendant's most-recently identified deficiencies have either been addressed by the EPPs or are not appropriate considerations at this time. As I find no valid reason to further delay the issuance of notice to the End Payor Class in this case, I will grant the EPPs' Motion. An appropriate Order follows.